Remarks

I. The Amendments

The specification of the application was amended to arrange sequence identification numbers. Attached hereto as an Appendix is a marked-up version of the text showing the changes that were made. It can be seen that, except for the sequence identification numbers, the original text has not been altered.

II. Submission of Computer Readable Form of Sequence Listing

Enclosed herewith is a 3.5 inch computer diskette containing a copy of the enclosed Sequence Listing in ASCII text.

III. Statements to Comply With Sequence Listing Rules

In compliance with 37 C.F.R. § 1.821(f), Applicants' undersigned attorney hereby states the content of the paper and computer readable copies of the Sequence Listing submitted herewith are the same. In accordance with 37 C.F.R. § 1.821(g), Applicants' undersigned attorney hereby states that the Sequence Listing submitted herewith does not add new matter to the application.

Conclusion

In light of the amendments and remarks above, Applicants submit that they have now fully complied with all Sequence Listing rules. It is therefore respectfully submitted that this application is now in condition for substantive review. If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (703) 905-2251.

Respectfully submitted,

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Appendix

Version with Markings to Show Changes Made

The specification has been amended herein to add sequence identification numbers. The changes that were made are shown below with the underlined words indicating text that was added.

On page 2-3 of the specification, the paragraph that starts on line 32 of page 2 and ends on line 20 of page 3 to read as follows:

> Regarding the nature of the peptide determined as "procalcitonin" in sepsis, it was in fact made clear from the outset in the above-mentioned patients that the specific peptide need not be completely identical to the known procalcitonin peptide of full length, which is formed in the thyroid glands as a calcitonin precursor. However, the question as to whether the procalcitonin formed in the case of sepsis differs from the procalcitonin formed in the thyroid glands remain unanswered to date. Possible differences were posttranslational modifications of the known procalcitonin, such as glycosylations, phosphorylations or modifications of the primary structure, but also modified, shortened or lengthened amino acid sequences. Since the analytical assay methods used to date did not reveal any differences between the procalcitonin known as the calcitonin precursor and the procalcitonin formed in the case of sepsis, it was provisionally generally assumed that the procalcitonin formed in the case of sepsis is identical to the calcitonin precursor and is thus a peptide having the known procalcitonin sequence of 116 amino acids (procalcitonin 1-116). **(SEQ. ID. NO: 1)**

On page 3-4 of the specification, the paragraph that starts on line 31 of page 3 and ends on line 5 of page 4 to read as follows:

> The starting point for the invention disclosed in the present Patent Application is the surprising discovery that the procalcitonin detectable in comparatively high

concentrations in the serum of patients in the case of sepsis and sepsis-like systemic infection is not the complete procalcitonin 1-116 comprising 116 amino acids but procalcitonin shortened at the amino terminus by a dipeptide but otherwise identical and having an amino acid sequence of only 114 **(SEQ. ID. NO: 3)** amino acids (procalcitonin 3-116).

On page 4 of the specification, the paragraph that starts on line 6 to read as follows:

The dipeptide missing in comparison with the complete procalcitonin has the structure Ala-Pro. The lack of a dipeptide comprising a proline residue as a second amino acid **(SEQ. ID. NO: 2)** of the amino terminus of the complete procalcitonin sequence led to the presumption that a specific peptidase might play a role in the production of the procalcitonin 3-116 detectable in the case of sepsis, that is to say the so-called dipeptidyl-(amino) -peptidase IV (DP IV or DAP IV or CD26).

On page 11 of the specification, the paragraph that starts on line 6 to read as follows:

For the fractions 50- 52 , in which the predominant procalcitonin immunoreactivity was to be found, it emerged that the peptides contained therein clearly have the following N-terminus (15 amino acids) :

Phe Arg Ser Ala Leu Glu Ser Ser Pro Ala Asp Pro Ala Th r Leu
(SEQ. ID. NO: 4)